

Remarks and Arguments

Interview

Applicant thanks the Examiner for the courtesy of conducting an interview on July 15, 2009. Claim amendments to overcome the outstanding rejections were discussed in the interview, and are reflected in the listing of claims above.

Additionally, Applicant identified support in the specification for the claim term “rosuvastatin” that overcomes the written description and indefiniteness rejections levied against this term.

Finally, Applicant and Examiner discussed rejoinder of withdrawn claims 3, 13, 14, and 22 upon the introduction of appropriate amendments to these claims.

Amendments to the Claims

Upon entry of the above amendments, claims 1, 3, 4, 7-14, and 18-22 will be pending in this case, claims 2 and 15 having been newly canceled. Claims 3, 13, 14, and 22 are withdrawn from consideration. Claims 1, 4, 7-12, and 18-21 are under examination.

Claim 1 is amended to recite testing a nucleic acid for the presence of a codon encoding alanine instead of valine at amino acid position 174 of SEQ ID NO: 1. Support for this amendment is found on page 3, lines 7-10, of the present specification.

Claim 1 is amended to delete recitation of testing for alleles in linkage disequilibrium with a codon encoding alanine instead of valine at amino acid position 174 of SEQ ID NO: 1. Claims 3 and 4 depend from claim 1, and have been amended to preserve proper antecedent basis.

Claim 11 is amended to recite determining whether the OATP-C polypeptide comprises an alanine instead of a valine at position 174 of SEQ ID NO:1. Support for this amendment is found on page 3, lines 7-10, of the present specification. Claims 12 and 14 depend from claim 11, and have been amended to preserve proper antecedent basis.

Claims 1, 11, 14, and 22 have been amended by removing the phrase “corresponding to.”

No new matter has been introduced as a result of the present amendments, each of which is made without prejudice. Applicant reserves the right to pursue any subject matter canceled as

a result of the present amendments in future prosecution, either in this application or in one or more continuing applications.

Specification

The Examiner has objected to the specification, asserting that amendments made to Table 1 on November 12, 2008 introduce new matter in violation of 35 U.S.C. §132(a). Specifically, the Examiner asserts the specification lacks support for the amendments made to the rows listing the amino acid changes in the *1b and *14 haplotypes. Applicant submits that the previous amendments to Table 1 were made merely to correct obvious typographical errors, and introduce no new matter.

Table 1 is entitled "Common Haplotypes in the OATP-C gene." The haplotypes listed in Table 1 (*1a, *1b, *5, *14, and *15) were previously known. Indeed, the present specification refers on page 18, lines 14-15, to a 2001 published paper by Tirona *et al.*, which describes the OATP-C *1b and *14 haplotypes listed in Table 1. An information disclosure statement that includes the Tirona *et al.* reference is submitted with the present response.

As can be seen in Figure 1 of Tirona *et al.*, both the *1b and *14 haplotypes contain the Asn130Asp allele. The amendments to Table 1 made November 12, 2008 were made merely to correct typographical errors in the listed alleles at amino acid position 130 of OATP-C, which alleles were previously known, and did not introduce new matter.

Applicant thus respectfully requests withdrawal of this objection.

Rejections under 35 U.S.C. §112, First Paragraph

Written Description

Claims 1, 4, 7-12, 15 and 18-21 were rejected under 35 U.S.C. §112, first paragraph, for lack of written description. The office action contained several specific written description rejections, each of which is addressed below.

First, the Examiner asserts that the specification lacks written description for codons encoding amino acids other than alanine at position 174 of SEQ ID NO:1, as recited in previously pending claim 1. Without conceding the merits of this rejection, Applicant has amended independent claim 1 to recite testing the nucleic acid for the presence, on at least one

allele, of a codon encoding alanine instead of valine at amino acid position 174 of SEQ ID NO:1. As such, this rejection is moot.

Second, the Examiner asserts that the specification lacks written description for all alleles in linkage disequilibrium with a codon containing alanine at position 174 of SEQ ID NO: 1, as recited in previously pending claim 1. Without conceding the merits of this rejection, Applicant has amended independent claim 1 to delete recitation of alleles in linkage disequilibrium with a codon encoding alanine instead of valine at amino acid position 174 of SEQ ID NO: 1. As such, this rejection is moot.

Third, the Examiner asserts that the specification lacks written description for amino acids other than alanine at position 174 of SEQ ID NO:1, as recited in claim 11 prior to the present amendment. Without conceding the merits of this rejection, Applicant has amended independent claim 11 to recite determining whether an OATP-C polypeptide comprises an alanine instead of a valine at position 174 of SEQ ID NO:1. As such, this rejection is moot.

Finally, the Examiner asserts that the specification lacks written description for the claim term "rosuvastatin." As discussed in the interview on July 15, 2009, the statin compound rosuvastatin is a widely known drug that is described on page 9, lines 24-27 of the specification. Just as one of ordinary skill in the art would know the term "alanine" and would be aware of its structure, one of ordinary skill in the art would similarly know the term "rosuvastatin" and would be aware of this compound's structure. One of ordinary skill in the art, upon reading the present application, would understand that that Applicant was in possession of the methods specified in the currently pending claims.

Applicant respectfully requests withdrawal of the rejections under 35 U.S.C. §112, first paragraph, for lack of written description

Enablement

Claims 1, 4, 7-12, 15 and 18-21 were rejected under 35 U.S.C. §112, first paragraph, for lack of enablement. Several specific enablement rejections were levied, including lack of enablement for all alleles in linkage disequilibrium with a codon containing alanine at position 174 of SEQ ID NO: 1, and lack of enablement for amino acids other than alanine at position 174

of SEQ ID NO:1. Without conceding the merits of these rejections, Applicant submits that the claim amendments described in detail above render these rejections moot.

Additionally, the Examiner asserted that the specification did not enable methods of using “rosuvastatin” since the specification did not define the term. As discussed in detail above, the specification describes the statin compound rosuvastatin on page 9, lines 24-27. Thus, one of ordinary skill in the art would be able to practice the claimed methods without undue experimentation.

Applicant respectfully requests withdrawal of the rejections under 35 U.S.C. §112, first paragraph, for lack of enablement

Rejections under 35 U.S.C. §112, Second Paragraph

Rosuvastatin

Claims 1, 4, 7-12, 15 and 18-21 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for reciting the term “rosuvastatin.” As discussed in detail above, rosuvastatin is a well-known compound with a well-defined structure (see specification at page 9, lines 24-27). One of ordinary skill in the art would understand what is meant by this term. Applicant respectfully requests withdrawal of this rejection.

“Corresponding to”

Claims 1, 4, and 7-10 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for reciting “a codon encoding alanine at a position corresponding to position 174 of SEQ ID NO: 1.” Similarly claims 11, 12, 15 and 18-21 were rejected under 35 U.S.C. §112, second paragraph as being indefinite for including the phrase an “amino acid corresponding to position 174 of SEQ ID NO: 1.”

Without conceding the merits of this rejection, independent claims 1 and 11 have been amended to delete the phrase “corresponding to.” Thus, these rejections are now moot, and Applicant respectfully requests their withdrawal.

Rejoinder

Applicant respectfully requests that withdrawn claims 3, 13, 14, and 22 be rejoined upon the allowance of independent claims 1 and 11, as currently amended. Withdrawn claims 3, 14, and 22 have been appropriately amended to preserve proper antecedent basis.

In light of the present amendments and arguments, Applicant submits that the present application is in condition for allowance, and respectfully requests a notice to that effect. If the Examiner feels that it would further prosecution or expedite allowance of the present case, she is invited to telephone the undersigned at 612-766-2071.

Please apply the \$1,110 extension of time fee and any the other charges, or credit any overpayments, to deposit account 06-1050, referencing Attorney Docket No. 06275-0492US1.

Respectfully submitted,

Date: August 10, 2009

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